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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/577,694	05/22/2000	Anne Sorensen	Novo-029	3706

7590

09/26/2002

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EXAMINER

HON, SOW FUN

ART UNIT	PAPER NUMBER
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1772

6

DATE MAILED: 09/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

AS-6

Office Action Summary	Application No. 09/577,694	Applicant(s) SORENSEN ET AL.	
	Examiner Sow-Fun Hon	Art Unit 1772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 21 and 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>1</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

1. Claims 21-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election of claims 1-20 was made **without** traverse in Paper No. 5 (filed 07/02/02).

Claim Objections

2. Claim 1 is objected to because of the following informalities: the phrase “compared t” should be retyped as “compared to”. Appropriate correction is required.

3. Claim 19 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. In the instant case, the recitation in claim 1 should replace the phrase “a stopper as defined in claim 1”.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 4, 7-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear by what method the hardness has been measured. The ASTM method with the year attached must be provided.

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6. Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term “substantially” is vague and indefinite.

7. Claims 17-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 17, the term “capable of” is vague and indefinite since it is indicative of intended use, and is not given any patentable weight. In claim 18, it is unclear what is meant by the claim limitation “applied force to the stopper is through a rod”. Does it mean that a rod is used to push the stopper in?

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Kasai et al. (US 4,444,330).

Kasai et al. teaches a stopper comprising 30 to 90 weight % partially crosslinked butyl based rubber and up to 30 weight % thermoplastic polyolefin. The polyolefin is taught to be polypropylene or polyethylene. The butyl based rubber is a halogenated one (column 1, lines 35-65 and column 3, lines 5-15) such as a bromobutyl rubber. Kasai et al. teaches that the butyl rubber alone is subject to permanent set and cannot provide a stopper for hermetically sealing a

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medical container (column 2, lines 15-65) thus teaching that a stopper made from a combination of the butyl rubber and another component provides for a hermetically sealed container resulting in a reduced leakage of substances compared to a stopper made from butyl rubber alone.

Because Kasai et al. teaches that the bromobutyl rubber is at least partially crosslinked, is blended with up to 30 % polypropylene or polyethylene, and that the stopper is injection molded, in the absence of clear comparative data, it is the examiner's position that the resultant stopper has a hardness of 40-80 Shore A.

Kasai et al. teaches a medical container with non-flexible walls (rigid) (column 1, lines 5-15). The figures show that the stopper has a circular cross-section, and that the container comprises a distal and a proximal end, and at least one wall defining an interior space for storing liquid medicament (figures and column 5, lines 40-60).

Even though product by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985). In the instant case, the stopper is in the container, and any way of pushing the stopper in, whether the applied force to the stopper is through a rod or palm of a hand results in a stoppered container.

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Any inquiry concerning this communication should be directed to Sow-Fun Hon whose telephone number is (703)308-3265. The examiner can normally be reached Monday to Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached on (703)308-4251. The fax phone number for the organization where this application or proceeding is assigned is (703)872-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0661.

PA

09/23/02


HAROLD PYON
SUPERVISORY PATENT EXAMINER
1772

9/23/02